# OPERATIONAL PROTOCOL

## A. ORGANIZATION AND STRUCTURAL ADMINISTRATION

### 1. Description Of The Organizational And Structural Administration That Will Be In Place to Implement, Monitor, And Operate The Demonstration, And The Tasks Each Organizational Component Will Perform

The state's Medicaid agency, South Carolina Department of Health and Human Services (DHHS) will directly administer and implement the waiver program. Within DHHS, the Division of Health Services' Department of Pharmacy Services (within the Bureau of Health Services and Delivery Systems) will have primary responsibilities regarding the implementation, monitoring, and operation of the waiver program. The Bureau of Beneficiary and Systems Support, Bureau of Information Systems, and the Bureau of Fiscal Affairs will be responsible for reporting and will also be responsible for the transition of waiver participants into the DHHS systems environment. The state-only funded senior prescription drug program that is currently operating (known, currently, as the South Carolina SILVERxCARD program; DHHS will continue to use the SILVERxCARD name for the Medicaid waiver prescription drug benefit program for seniors) employs a contractor (ACS) to perform eligibility functions and the processing of pharmacy claims. This contractor (ACS) will continue to perform the eligibility functions for the waiver program, but will not process pharmacy claims for waiver participants. Currently, DHHS has a contract with First Health Services Corporation to operate the pharmacy point of sale system, process Medicaid pharmacy claims, perform prospective drug utilization review, and perform prior authorization functions. This contractor (First Health) will be responsible for these same functions (that are performed for Medicaid beneficiaries) for prescriptions dispensed to waiver participants.

### 2. Timeline Of Demonstration Implementation Tasks Prior To And Post Implementation, Including Steps, Estimated Time Of Completion, Who Will Be Responsible (Necessary Pre-Implementation Data Systems Changes, When Edits Will Be Made, When Changes Will Be Tested, And The Responsible Party)

| TIMELINE OF IMPLEMENTATION TASKS | | |
|---|---|---|
| **DATE** | **TASK** | **AREA OF RESPONSIBILITY** |
| January 8, 2002 | Submit Medicaid 1115 Research and Demonstration Waiver Application to CMS | Office of Research and Development |
| July 26, 2002 | Receive approval of Demonstration Waiver | SCDHHS |
| August 2002 – September 2002 | Compile Operational Protocol Information | Beneficiary and Systems Support<br>Fiscal Affairs<br>Health Services<br>Information Systems<br>Research & Development |
| September 11, 2002 | Meet with contractor for current prescription drug program for low-income seniors | Implementation Team |
| September 19, 2002 | Submit Operational Protocol to CMS | SCDHHS |
| September 2002 | Receive tapes/diskettes of participants currently enrolled in the prescription drug program for low-income seniors | Beneficiary and Systems Support<br>Information Systems |
| September 2002 – October 2002 | Prepare and finalize requirements analysis for DHHS Pharmacy Services' contractor for claims processing, prospective drug utilization review, prior authorizations | Beneficiary and Systems Support<br>Health Services<br>Information Systems<br>Contractor for claims processing |
| October 2002 | Begin the year-round enrollment of new participants in the waiver program (current participants in the state-only funded current prescription drug program for low-income seniors will be "grandfathered" into the waiver program) | Beneficiary and Systems Support<br>Health Services<br>Information Systems<br>Contractor for eligibility |
| October 2002 | Initiate outreach/marketing programs and disseminate application materials to participants | Beneficiary and Systems Support<br>Health Services<br>Contractor for eligibility |
| November 2002 | Prepare drafts of new outreach/marketing materials for review by CMS | Health Services |

| TIMELINE OF IMPLEMENTATION TASKS | | |
|---|---|---|
| **DATE** | **TASK** | **AREA OF RESPONSIBILITY** |
| November 2002 | Testing | Beneficiary and Systems Support<br>Health Services<br>Information Systems<br>Contractor for claims processing |
| November 2002 – December 2002 | Inform public health clinics, FQHCs, rural health clinics, and triage clinics for uncompensated care at disproportionate share hospitals of intent to direct low-income seniors to those facilities if those seniors are unable to find and use traditional primary care health providers | Health Services |
| November 2002 – December 2002 | Disseminate educational outreach materials to pharmacy providers, pertinent organizations | Health Services |
| December 2002 | Finalize systems testing | Beneficiary and Systems Support<br>Health Services<br>Information Systems<br>Contractor for claims processing |
| January 1, 2003 | Implementation | SCDHHS |

| DHHS IMPLEMENTATION TEAM | |
|---|---|
| ***Area of Responsibility*** | ***Implementation Contact Persons*** |
| Beneficiary and Systems Support | Gail Buchanan, Alicia Jacobs |
| Fiscal Affairs | Robby Kerr, Clarence Lewis, Milton German, Renee Herndon, Calvin Nesbit, William Wells |
| General Counsel | Byron Roberts |
| Health Services | James Assey, Ray Sharpe, Caroline Sojourner |
| Information Systems | Rod Davis, Rhonda Morrison |
| Office of Research and Development | Paula Fendley, Larry Fernandez |

## 3. Claims Processing

Pharmacy claims for waiver participants will be processed by DHHS' current Medicaid pharmacy claims processing contractor.

## 4. Pharmacy Benefit Management Approaches

The pharmacy benefit for waiver participants will be managed using the same policies, systems, techniques, and programs that are in place for Medicaid beneficiaries. Currently, the methods used to manage the pharmacy benefit include:

a) Drug Utilization Review (DUR) Programs - Retrospective DUR and Prospective DUR
b) Pharmacy Prior Authorization Program
c) State Maximum Allowable Cost Program
d) Federal Upper Limits of Payment Program
e) Medicare-Covered Drugs Billing Requirement
f) Dispensing Limitations

## 5. Reimbursement Rates And Dispensing Fees

Pharmacies enrolled as South Carolina Medicaid providers will also be providers to waiver participants. As with the Medicaid program, pharmacies are enrolled as providers within the program while the beneficiaries are considered as participants. These pharmacy providers will be responsible for dispensing covered prescriptions to waiver participants. Covered prescriptions for all demonstration waiver participants will be reimbursed at the same Medicaid pharmacy reimbursement rate and dispensing fee as reflected in the approved State Plan.

### 1) Reimbursement Rates

The provider reimbursement rate for prescriptions dispensed to waiver participants will be the same Medicaid reimbursement formula as included in the approved State Plan. Following is the Medicaid prescription reimbursement rate that will also be applicable to SILVERxCARD prescriptions:

The amount reimbursed to the pharmacy provider for the prescription dispensed shall not exceed the lowest of:

a) The federally mandated upper limit of payment (FUL) or state Maximum Allowable Cost (MAC) for the drug, if any, less 10% plus the dispensing fee as established in accordance with federal requirements.

b) The South Carolina estimated acquisition cost (SCEAC),

which is average wholesale price (AWP) less 10% plus the dispensing fee.

c) The provider's usual and customary charge to the general public for the prescription as written for the product actually dispensed.

**2) Dispensing Fees**

The same dispensing fee, as reflected in the approved State Plan, is applicable to prescriptions dispensed to Medicaid beneficiaries and will also be applicable to prescriptions dispensed to waiver participants.

**3) Co-Payments**

The pharmacy provider will collect the co-payment when the prescription is dispensed. This co-payment serves as part of the provider's total prescription reimbursement. DHHS will reimburse the provider for the difference between the total amount owed for the prescription, based on DHHS' approved reimbursement formula, and the specified co-payment amount required of the participant. Waiver participants will be required to make the designated co-payment in order to obtain the covered prescription. The co-payment must be paid to the pharmacy at the time that the prescription is received. If the waiver participant does not make the prescription co-payment, then the pharmacy may choose to not dispense the prescription to the SILVERxCARD participant.

Waiver participants are defined as those non-Medicaid eligible individuals who have no other prescription drug coverage, are aged 65 and over, and have incomes at or below 200% of the Federal Poverty Level. For these waiver participants, the following co-payment schedule becomes effective after the annual deductible amount of $500 has been met:

| | |
|---|---|
| Generic drugs | $10.00 |
| Brand drugs | $15.00 |
| Drugs requiring prior authorization | $21.00 |

**4) Deductible**

Beginning with each calendar year, waiver participants become eligible for SILVERxCARD drug coverage after paying a total of $500 (the deductible amount) out of pocket for drugs and products that are covered in the South Carolina Medicaid Pharmacy Services program. During the deductible period, covered prescription drugs may be purchased at a rate that is no more than the reimbursement rate paid by Medicaid. The waiver participant must pay his/her share of the drug cost at the time of purchase in order for the prescription cost to be counted towards the $500 deductible. Waiver participants' out of pocket prescription payments count towards the deductible as the prescriptions are purchased at the pharmacy. Once the $500 annual deductible has been met, waiver participants will be eligible to receive those same pharmacy services available to Medicaid beneficiaries served by the Medicaid program.

**5) Enrollee Cost Sharing Collections**

A requirement for waiver participation is that participants have no other prescription coverage; therefore, this section is not applicable to the Prescription Drug Benefit for South Carolina's Low Income Seniors waiver. Additionally, an annual deductible amount of $500 must be met before qualifying for the waiver program's prescription drug benefit.

**6) Rebate Arrangements**

Only those pharmaceuticals of those manufacturers participating in the Federal Drug Rebate program will be covered in the waiver program. Rebates will be collected only when Medicaid issues reimbursement for a covered prescription drug (i.e., rebates will not be collected for drugs obtained by a participant in his or her deductible period).

At this time, the state does not plan to enter into any separate rebate arrangements with individual pharmaceutical companies; however, if the state does enter into separate rebate agreements:

- Pharmaceuticals dispensed to Medicaid beneficiaries, will include waiver participants' prescriptions.
- The supplemental rebate agreement will be submitted in a State Plan Amendment for CMS approval.
- All supplemental rebates will be reported to CMS.

## B. REPORTING ITEMS

South Carolina Medicaid's 1115 Research and Demonstration Waiver – A Prescription Drug Benefit for South Carolina's Low-Income Seniors (the SILVERxCARD program) received CMS approval July 30, 2002. DHHS understands that a limit has been placed on the number of SILVERxCARD participants that may be served under the waiver. Eligibles are defined as those SILVERxCARD beneficiaries who meet the eligibility requirements to enroll in the waiver program. A subset of this group of eligibles are the SILVERxCARD participants, or the more appropriate term may be SILVERxCARD utilizers. SILVERxCARD participants/utilizers are those eligibles who have met the deductible and are utilizing (or, participating in) the prescription drug benefit. It is during the post-deductible period that the enrollee will begin receiving prescriptions that are covered by the waiver, not by the enrollee.

CMS has limited the number of SILVERxCARD participants (not total eligibles/enrollees) who are utilizing the drug benefit to 66,000 individuals at a per member per month (PMPM) rate of $159. This dollar amount reflects the average cost of an individual who has started receiving services under the full demonstration benefit. The limit of 66,000 does not include individuals in their deductible period. Those individuals are not counted until they meet their deductible and actually start receiving benefits under the waiver.

### 1. Monthly Progress Calls

a) Progress Calls Prior To And Immediately Following Waiver Implementation

Conference calls regarding approval of Operational Protocol will be on an "as needed" basis.
The Department of Health and Human Services (DHHS) will conduct a progress call with CMS on an "as needed" basis to discuss demonstration progress prior to and immediately after the initial implementation date. Discussions will focus on:

- Obtaining clarification on items of concern
- Status updates
- Other issues affecting implementation and/or operation

b) Progress Calls Throughout The Demonstration Waiver

"As needed" calls may continue throughout the demonstration waiver for the required timeframe and beyond if necessary.

### 2. Quarterly And Annual Progress Reports

DHHS will submit draft quarterly and annual progress reports, which will address:

- Demonstration events to include enrollment statistics and expenditure data
- Notable accomplishments and acquired knowledge
- Problem areas with recommended resolutions

Reports will be submitted 60 days after the end of each quarter. The fourth quarter report will include a summary of the past year highlighting accomplishments and lessons learned for future application.

**3. Final Reports**

DHHS will submit a draft final report, patterned in format with CMS author guideline "Grants and Contract Final Reports," to CMS for review. Any recommended comments by CMS will be incorporated into the final report and used to enhance program deliverables. Final reports will include evaluation results of demonstration outcomes toward intended goals.

**4. General Financial Requirements**

DHHS will prepare quarterly expenditure reports using the Form CMS-64 to report total expenditures for services provided under the Medicaid program, including those provided through the demonstration under section 1115 authority.

DHHS will report demonstration expenditures through the Medicaid and State Children's Health Insurance Program Budget and Expenditure System (MBES/CBES), following routine CMS-64 reporting instructions outlined in Section 2500 of the State Medicaid Manual. Applicable rebates and expenditures subject to the budget neutrality cap will be reported on separate Forms CMS-64.9 WAIVER and/or 64.9P WAIVER, identified by the demonstration project number assigned by CMS (including the project number extension, which indicates the demonstration year in which services were rendered). For monitoring purposes, cost settlements will be recorded on Line 10.b, in lieu of Lines 9 or 10c. For any other cost settlements (i.e., those not attributable to this demonstration), the adjustments should be reported on lines 9 or 10.c, as instructed in the State Medicaid manual. DHHS will accomplish this by creating and maintaining separate source documents for easy retrieval and reporting. The term, "expenditures subject to the budget neutrality cap," is defined below in item 1.a.i.

1. For each demonstration year, a Form CMS-64.9 WAIVER and/or 64.9P WAIVER will be submitted reporting expenditures for individuals enrolled in the demonstration. The expenditures for the non-demonstration aged group will be reported through the CMS-64.9 WAIVER reporting system for budget neutrality purposes (including expenditures for this group under all other waiver authorities (i.e., 1915(b), 1915(c), 1115, etc.)). The sum of the

quarterly expenditures for these two groups, for all demonstration years, will represent the expenditures subject to the budget neutrality cap (as defined in 1. a.i.).

a. Based on identifiers assigned during eligibility, applicable recipient expenditure data will be summarized on a separate source document to support reported information on the CMS 64.9 and CMS-64.9P waiver forms. Non-demonstration recipients will be identified using other selection criteria, and will also be summarized on a separate source document for reporting purposes.

i. For the purpose of this section, the term "expenditures subject to the budget neutrality cap" will include all Medicaid expenditures on behalf of individuals who are enrolled in the demonstration and all expenditures made for service costs for the non-demonstration aged Medicaid eligibility group. All expenditures that are subject to the budget neutrality cap are considered demonstration expenditures and will be reported on Form CMS 64.9 WAIVER and/or 64.9P WAIVER.

2. DHHS will separately track and report additional administrative costs that are directly attributable to the demonstration. All administrative costs will be identified on the Forms CMS-64.10 WAIVER and/or 64.10P WAIVER.

a) Separate identifiers will be created to capture administrative costs associated with the demonstration. Such identifiers will be incorporated with existing source documents as support for routine and waiver administrative reporting. Standard operating procedures will be followed.

3. When discovered timely, all claims for expenditures subject to the budget neutrality cap (including any cost settlements) will be made within 2 years after the calendar quarter in which DHHS made the expenditures. Furthermore, all claims for services during the demonstration period (including any cost settlements) will be made within 2 years after the conclusion or termination of the demonstration. During the latter 2 year period, DHHS will continue to identify separately net expenditures related to dates of service during the operation of the 1115 demonstration on the Form CMS-64 in order to properly account for these expenditures in determining budget neutrality.

The standard Medicaid funding process will be used to request demonstration funding. DHHS will estimate matchable Medicaid expenditures on the quarterly Form CMS-37. As a supplement to the Form CMS-37, DHHS will provide updated estimates of expenditures

subject to the budget neutrality cap as defined in 1.a.i above. The CMS will make Federal funds available based upon this estimate, as approved by CMS. The CMS will reconcile expenditures reported on the Form CMS-64 with Federal funding previously made available through the CMS-37 process, and include the reconciling adjustment in the finalization of the grant award to DHHS.

DHHS will certify State/local monies used as matching funds for the demonstration and will further certify that such funds will not be used as matching funds for any other Federal grant or contract, except as permitted by Federal law.

Any enrollee cost sharing collections will be used appropriately to reduce program expenditures prior to determining the level of FFP.

## C. COST SHARING REQUIREMENTS

Provider reimbursement requirements and policies within the waiver program will duplicate those same requirements and policies within the Medicaid program. As with Medicaid beneficiaries, once a provider has accepted an eligible as a participant in the waiver/Medicaid program, the provider must accept the amount established by the Medicaid program as payment in full. Medicaid payments will be made only to a provider; there is no option for reimbursement to a beneficiary.

Regarding waiver participants' deductible period, providers may not charge enrollees any more for a prescription than the reimbursement rate paid by Medicaid. Those payments made by waiver participants for prescriptions purchased at the pharmacy are counted by DHHS as payments toward the deductible. If a person does not pay his/her share of the drug cost at the time of purchase, then the cost cannot be counted towards the deductible.

After the deductible has been met, waiver participants are required to pay prescription co-payments at the time that drugs are received. If the co-payment is not paid at the time of dispensing, then the provider may choose to not dispense the prescription to the enrollee. Enrollees will be informed of cost-sharing policies in the educational materials disseminated by DHHS and the eligibility contractor.

## D. COORDINATION WITH PRIVATE HEALTH INSURANCE COVERAGE

A requirement for waiver participation is that participants have no other prescription coverage; therefore, this section is not applicable to the Prescription Drug-Benefit for South Carolina's Low-Income Seniors waiver.

## E. PHARMACY SERVICES, PROVIDERS, AND BENEFIT MANAGEMENT

### 1. Pharmaceutical Services That Are Included In The Demonstration, Including a Description of Services To Be Provided During An Enrollee's Deductible Period

Participants in the waiver pharmacy benefit will pay a $500 deductible out of pocket for drugs and products that are covered in the South Carolina Medicaid Pharmacy Services program. As required by Section 1927, OBRA 1990, and as described in the approved State Plan, the Medicaid program covers most rebated legend and some non-legend generic, rebated pharmaceuticals that are authorized by prescription. During the deductible period, participants will pay no more for a prescription than the reimbursement rate paid by Medicaid.

Once the $500 annual deductible has been met, waiver participants will be eligible to receive those same pharmacy services available to Medicaid beneficiaries served by the Medicaid program. Participants will be limited to four prescriptions per month. Certain products and product categories are exempt from the monthly prescription limitation. Information regarding exemptions from the monthly prescription limit is communicated to providers in Medicaid provider bulletins.

For those participants needing more than four prescriptions within a given month, a prescription limit override process is available for those prescriptions that meet the prescription limit override criteria. Information regarding the prescription limit override criteria is communicated to providers in Medicaid provider bulletins.

Non-controlled substance prescriptions are limited to a maximum 34 days' supply per prescription/refill. The dispensed quantities of controlled substance prescriptions are limited by state and federal regulations as detailed in the Controlled Substance Act.

Those same products that require prior authorization for Medicaid eligibles will require prior authorization for waiver participants, meaning that coverage is determined through the previously established prior authorization process. DHHS uses a contractor to provide prior authorization services. Providers are informed of those products requiring prior authorization in Medicaid provider bulletins.

### 2. Method Of Services Provision

Medicaid-enrolled pharmacy providers will provide pharmacy services to participants.

### 3. Detailed Description Of The Pharmacy Benefit Management Approaches

a) Drug Utilization Review (DUR) Programs

Retrospective DUR involves monthly reviews of patient drug history profiles by a panel of physicians and pharmacists *after* the prescription has been dispensed. The patient drug history profiles are evaluated for a variety of possible drug therapy problems including: therapeutic appropriateness, over and underutilization, therapeutic duplication, drug-disease contraindications, drug-drug interactions, incorrect dosage or duration of therapy.

Prospective DUR involves a review of the patient's drug therapy and prescription drug order as part of a drug regimen review before the prescription is filled or dispensed. The Medicaid point of sale system's on-line prospective DUR system assists the pharmacist evaluating the prescription to be dispensed for a number of potential drug therapy conflicts [e.g., therapeutic appropriateness, under and over-utilization (or, early refill attempt and late refill), therapeutic duplication, drug-disease contraindications, drug-drug interactions, incorrect dosage or duration of therapy]. Drug utilization review performed before to dispensing serves as an important tool in managing the pharmacy benefit.

b) Pharmacy Prior Authorization Program

A pharmacy prior authorization (PA) program is maintained to ensure appropriate prescribing of medically necessary drugs. For example, the PA program ensures that brand name; multi-source drugs are covered for only those enrollees that have realized a treatment failure on a generic version of the specific multi-source drug. Or, as another example, the PA program ensures that (for certain drugs or drug categories) the newest (and, in many cases, the most costly) is not used as the first drug of choice when one of the precursor drugs may be satisfactory or appropriate protocol before use of the newest drug on the market.

The PA program functions by requiring that prescribers contact (via telephone or fax) the pharmacy prior authorization call center to request coverage of certain products that they are planning to prescribe. Based on criteria established by DHHS and the contractor's clinicians, the contractor makes the determination regarding coverage of the product. The contractor employs a clinical staff of pharmacists and pharmacy technicians with primary responsibilities that include responding to prescribers' prior authorization requests.

As included in the approved State Plan, DHHS provides response by telephone or other telecommunication device within 24 hours of a request for prior authorization and provides for the dispensing of at least 72-hour supply of a covered outpatient prescription drug in an emergency situation.

c) State Maximum Allowable Cost (MAC) Program:
The state maximum allowable cost program assists in managing the pharmacy benefit by controlling costs through the encouragement of use of available generic products. The MAC is applied to those products with generic availability to encourage the use of the least costly generic products. Within this program, regardless of manufacturer of the generic product or the listed Average Wholesale Price (AWP), the state will reimburse no more than the state-established MAC.

d) Federal Upper Limit (FUL) of Payment Products:
In addition to the state MAC program, DHHS also adheres to CMS' listing of products with federal upper limits of payment. The objectives of the FUL program are identical to those of the state MAC program.

e) Medicare-Covered Drugs:
DHHS manages the pharmacy benefit by requiring pharmacists to bill Medicare as primary for those prescriptions for Medicare-covered drugs for dually eligibles.

f) Days' Supply Per Prescription/Refill
The pharmacy benefit is managed through the disallowance of coverage for non-controlled substance prescription quantities that exceed a 34 days' supply. Participants will be limited to four prescriptions per month.

## 4. Pharmacy Access And Payment

### a) Ensure Access To An Adequate Number of Pharmacies

All pharmacies enrolled as providers in the South Carolina Medicaid program may provide pharmacy services to participants in the waiver. A pharmacy (either in-state or out of state) may enroll as a South Carolina Medicaid provider if it has a pharmacy permit from its respective Board of Pharmacy and a pharmacist who maintains, compounds, and dispenses prescription drugs and devices for patients and provides pharmacy-related services. Additionally, non-resident pharmacies (i.e., pharmacies located outside of South Carolina) whose primary business is filling mail order prescriptions may enroll as a S. C. Medicaid provider after obtaining a special permit issued by the South Carolina Board of Pharmacy in order to engage in the sale, distribution, or dispensing of legend drugs or devices in South Carolina. There are approximately 1,080 pharmacies enrolled as S. C. Medicaid providers. In addition to in-state pharmacies, South Carolina Medicaid enrolls both out of state and mail order pharmacies. It is estimated that at least 95% of the retail pharmacies in South Carolina are enrolled as pharmacy

providers, therefore, participants are assured of adequate access to pharmacies.

**b) Description of Payments to Pharmacies During An Enrollee's Deductible Period**

The participant will present the waiver program identification card at the pharmacy along with the prescription. The Medicaid point of sale system will confirm eligibility and communicate whether the participant has met the deductible. If the deductible has not been met, then the participant is responsible for the prescription payment. During this deductible period, participants will pay no more for a drug than the reimbursement rate paid by Medicaid. The computerized system will maintain a participant-specific calculation of the prescription payment amounts paid by the participant. All prescription information and data (drug, quantity, amount paid, etc.) accumulated during the deductible period will be considered as "encounter claims" and will be maintained by the computerized system and DHHS for reporting and monitoring purposes. Rebates will not be collected for drugs obtained by a participant in his/her deductible period.

## 5. Methodology For Determining Reimbursement To Pharmacy Providers

The participant will be responsible for prescription reimbursements until the $500 annual deductible has been met. After the annual deductible has been met, Medicaid will be responsible for provider reimbursement, less the co-payment amount paid by the participant, for covered prescriptions.

The pharmacy provider should submit the pharmacy's usual and customary charge when billing for a prescription dispensed to a participant in the waiver. The amount reimbursed to the pharmacy provider for the prescription dispensed shall not exceed the lowest of:

a) The federally mandated upper limit of payment (FUL) or state Maximum Allowable Cost (MAC) for the drug, if any, less 10% plus the current dispensing fee as established by the DHHS in accordance with federal requirements.

b) The South Carolina estimated acquisition cost (SCEAC), which is average wholesale price (AWP) less 10% plus the current dispensing fee.

c) The provider's usual and customary charge to the general public for the prescription as written for the product actually dispensed.

In those instances where the participant's co-payment amount exceeds the calculated reimbursement total, the pharmacy provider will collect the

allowed amount as the co-payment for that prescription rather than collecting the entire co-payment amount.

## 6. Interaction Of A State Only Funded Program And The Demonstration Waiver Program

The currently existing state-only-funded Prescription Drug Benefit for South Carolina's Low-Income Seniors will no longer be maintained as a state-only-funded program. This program will become the demonstration waiver administered by the state's Medicaid program.

DHHS will inform SILVERxCARD participants in the current state-only-funded Prescription Drug Benefit of the change in their prescription drug coverage through the distribution of "Welcome Packet" information. The initial waiver program distribution of the Welcome Packet describing the prescription drug benefit, to include the plan summary, benefits, and limitations, will occur December 2002. The Welcome Packet will be sent to all eligibles enrolled in the SILVERxCARD as of December 2002. New enrollees will receive their new program identification cards along with the Welcome Packet information. Those individuals who were SILVERxCARD enrollees prior to October 2002 (when year-round open enrollment began) will receive the Welcome Packet information only since those enrollees will continue to use their existing identification cards. Eligibles that enroll with SILVERxCARD after the December 2002 distribution will receive the Welcome Packet along with the waiver program identification card.

The Welcome Packet includes information regarding:

- Deductible
- Co-payment
- Pharmacy providers
- Drug coverage (covered items, non-covered products)
- Benefits
- Limitations

## 7. How Any Accompanying Pharmacy Service, Such As PA, Will Be Utilized Under The Demonstration

Certain products require prior authorization (PA), meaning that coverage is determined through a prior authorization process. DHHS uses a contractor (currently, First Health) to perform all pharmacy PA functions. The PA call center is available 24 hours per day, 7 days per week.

For certain products, prescribers are required to contact the PA contractor to request coverage of the product that they are planning to prescribe. Listings of those prior authorization drug products have been made available to providers in Medicaid bulletins. DHHS will continue to inform providers of those products requiring prior authorization drugs through

bulletins. There are plans to use web site postings and personal educational interventions (either on-site or via the telephone) with providers. Upon receipt of a PA request from a prescriber, the contractor makes the determination regarding coverage of the product for the participant. The contractor is required to use a clinical staff of pharmacists and pharmacy technicians to respond to prescribers' PA requests.

In compliance with Section 1927 and as provided in the approved State Plan, the contractor assures that the state's PA program provides response by telephone or other telecommunication device within 24 hours of a request for prior authorization and provides for the dispensing of at least 72-hour supply of a covered outpatient prescription drug in an emergency situation.

## F. RELATED MEDICAL MANAGEMENT

### 1. Description Of The Mechanism In Place to Ensure That Demonstration Participants Utilizing Services Have Access To Basic Primary Care Health Services That Assist With Medical Management Related To Prescribed Pharmacy Products

Participants in the waiver program must be 65 years of age or older and are, therefore, most will be Medicare-eligible. Participants will access basic primary care services through those same processes available to all Medicare eligibles.

### 2. Information About Access For Enrollees With Medicare Versus Access For Individuals Who Are Eligible For The Demonstration But Not Eligible For A Medicare Primary Care Benefit

The vast majority of the waiver participants will be Medicare-eligible; however, any participants not receiving the Medicare benefit will utilize public health clinics under the direction of the South Carolina Department of Health and Environmental Control (DHEC), federally qualified health centers (FQHCs), rural health clinics, triage clinics for uncompensated care at disproportionate share hospitals, and free medical clinics that are located within the state. Through the use of Medicaid bulletins, these entities will be notified of the SILVERxCARD program. In order to prepare health care facilities for the potential impact of the medical management portion of the demonstration waiver, the South Carolina Primary Health Care Association will be notified through Medicaid bulletins and memos.

## G. OUTREACH/MARKETING/EDUCATION

DHHS understands and accepts that all marketing materials and enrollment material must be reviewed and approved by CMS prior to use. Information will be communicated to enrollees, participating providers, and State outreach/education/intake staff (such as social services workers and caseworkers, or contracted parties).

The SC SILVERxCARD program's application includes a tear-off brochure that lists eligibility criteria, rights and responsibilities, frequently asked questions and the toll-free SILVERxCARD hot line number, which is available 24 hours a day, seven days a week. A SILVERxCARD marketing poster is made available to all applications outlets (Councils on Aging, Legislative Delegation Offices, libraries, county-based Medicaid eligibility offices and pharmacies). These posters educate seniors on SILVERxCARD eligibility, the application process and the 24-hour hot-line number. The brochures and posters are used in various informational forums to inform senior groups, churches, legislative constituent meetings and health fairs about the SC seniors' prescription drug program.

Information is also communicated through the SILVERxCARD Internet web site – www.silverxcard.com. This site includes sections on eligibility, frequently asked questions, application assistance available, contact numbers and an online application

- The state outreach programs that will inform individuals of their potential eligibility for non-demonstration Medicaid, Medicaid assistance with Medicare cost sharing, and other programs,

If a SILVERxCARD applicant is denied because they are deemed ineligible, they frequently ask for assistance with other prescription drug programs. SILVERxCARD has utilized the SC Department of Health and Human Service's I-CARE program, which has a statewide toll-free number available for seniors. The staff of this office has applications and contact numbers available for programs related to pharmacy discounts, programs that assist the disabled, or free drug programs.

If a SILVERxCARD applicant is initially denied eligibility because the household income amount is below 100 % of the federal poverty level, they are contacted giving them the option to apply for Medicaid or to choose the SILVERxCARD program. This letter includes the local offices where seniors can apply for Medicaid and the toll-free hot line number they can call to continue the application process for SILVERxCARD.

- Types of media to be used;

In the past, the governor of SC has participated in a SILVERxCARD public service announcement (PSA). We plan to continue to utilize public service announcements. The PSAs include information concerning open enrollment, eligibility criteria and the toll-free telephone number for the SILVERxCARD hotline. These PSAs are shown statewide on all television affiliates listed in the SC television media guide including educational television.

Press conferences will be held with the governor announcing open enrollment. These conferences include a question and answer segment for the governor and SILVERxCARD staff. Past press conferences have generally been held in the capitol city of SC, Columbia and are covered by the Associated Press. Coverage by the Associated Press has resulted in statewide coverage. Additionally, the governor may travel around the state of SC making similar announcements. The audience at these press conferences is frequently senior citizen groups targeted as potential SILVERxCARD applicants.

Press releases have been issued the last two years to inform potential SILVERxCARD members of issues related to SILVERxCARD such as enrollment and plan design. We plan to continue to issue press releases to inform SILVERxCARD applicants about the program's enrollment period, eligibility criteria and plan design.

Articles have been written on SILVERxCARD in Healthwise newsletter, which is issued to Medicare beneficiaries. The staff at Carolina Medical Review (CMR) has contacted SILVERxCARD staff to write another article on SILVERxCARD program changes for December 2002. Quality Partners is a magazine also published through Carolina Medical Review. SILVERxCARD has been featured in a previous Quality Partners issue. CMR has contacted SILVERxCARD staff to cover the program, information on the federal waiver and program changes for an upcoming issue. Quality Partners is issued in the states of North and South Carolina to insurance providers, health care providers and others in the health care industry.

SILVERxCARD has an Internet web site – www.silverxcard.com that includes a section on eligibility, frequently asked questions, application assistance available, and an online application.

- Specific geographical areas to be targeted;

The entire state of South Carolina is targeted for marketing and outreach. Press conferences, press releases and application outlets are in all geographic areas of South Carolina. The web site and toll-free hot-line number is available statewide and assistance is available for applicants at each local Council on Aging.

The Councils on Aging (COA) play an important role in targeting the rural areas of South Carolina. Along with assisting SILVERxCARD applicants in each COA office, the COA staff will hand deliver SILVERxCARD applications to the homebound through its Meals on Wheels program. Through these visits, they will assist the homebound in these rural areas with filling out the applications. The COAs will then submit the application to the contractor.

SILVERxCARD staff is available to speak or assist applicants in all areas of South Carolina. Staff will participate at senior church meetings and local constituent meetings in all areas of our state. The SILVERxCARD program is explained and seniors are assisted in completing SILVERxCARD applications. SILVERxCARD staff forwards these applications to the contractor for processing.

- Locations where such information will be disseminated;

Information will be distributed state wide at all SILVERxCARD outlets which include pharmacies in the SILVERxCARD pharmacy network, county libraries, legislative delegation offices, Department of Social Services offices and Department of Health and Human Services offices.

- Staff training schedules, schedules for State forums or seminars to educate the public; and

SILVERxCARD staff will meet with the HHS I-CARE staff to inform them of changes related to the program and any instructions related to the upcoming application process. In the past, the COAs were educated and trained to assist

seniors with the SILVERxCARD application process. SILVERxCARD staff and the contractor staff are available year-round to assist the COAs in any way as they continue to assist SILVERxCARD applicants.

SILVERxCARD staff will continue to participate in assisting seniors at health fairs, constituent meetings and seniors' church meetings. SILVERxCARD staff and the contractor staff are available year-round to assist any senior group or interested party in speaking engagements, educational forums/seminars or assisting groups in applying for SILVERxCARD.

- The availability of bilingual materials/interpretation services and services for individuals with special needs. Include a description of how eligibles will be informed of cost sharing responsibilities.

The contractor has ten bilingual help desk staff members available on the SILVERxCARD toll-free hotline. If an applicant needs SILVERxCARD materials in another language, the contractor will provide them with an application or brochure written in that particular language. Welcome packets and any letters concerning SILVERxCARD eligibility will be sent to these applicants in their language. Bilingual staff at the contractor can also call applicants if additional information or corrections are needed concerning a SILVERxCARD application.

Once a SILVERxCARD applicant is deemed eligible, they are mailed a welcome packet. These packets explain the SILVERxCARD program and all aspects of the SILVERxCARD plan design. Cost sharing responsibilities such as deductibles and co-payments are included in plan design data.

Hearing impaired SILVERxCARD applicants can be assisted through the TDD number available through the contractor.

## H. ELIGIBILITY/ENROLLMENT

**Population of Individuals Eligible:** To be eligible for prescription drug service under this 1115 Research and Demonstration waiver program, an individual:

- Must be a resident of the state of South Carolina;
- Must meet citizenship and alienage requirements;
- Cannot be an inmate or a resident of a public institution;
- Must be age 65 or older;
- Must have gross household income at or below 200 percent of the federal poverty level. Income is defined as anything an individual receives in cash that can be used to meet the individual's need for food, clothing, or shelter (i.e., wages, Social Security, pension, veterans benefits, unemployment benefits). Items that are not considered as income under Medicaid rules are not included in the definition of income for this waiver program (i.e., VA Aid and Attendance, proceeds of the sale of an asset, proceeds from a loan, etc.
- Must have no prescription drug coverage.

There will be no asset test related to eligibility for the waiver program, and there will be no estate claims for services provided under this waiver.

**Eligibility Determination:**

South Carolina will continue to contract with ACS for the eligibility determination process. Applications will be accepted in person, by mail, and electronically over the Internet at www.silverxcard.com. SILVERxCARD eligibility is determined through self-declaration. Currently, pharmacy reporting serves as the primary method of eligibility verification. Pharmacy providers have direct contact with enrollees and those individuals may report any eligibility discrepancies to the state. Following the implementation of SILVERxCARD as a waiver program, DHHS will use data matches to perform eligibility verification.

Individuals applying for the waiver will be screened to determine if they are potentially eligible for non-demonstration Medicaid and, if found potentially eligible, will be informed of their option to receive pharmacy services only through the waiver or to receive the full range of Medicaid benefits, including pharmacy services, through non-demonstration Medicaid. An individual cannot receive benefits through the waiver and through the non-demonstration Medicaid program.

An individual who has been receiving coverage under non-demonstration Medicaid may, upon redetermination, be found ineligible for non-demonstration Medicaid and be evaluated for waiver participation. If found to be potentially

eligible for the waiver, the individual will be provided information regarding the waiver and referred to the toll-free help desk number, 1-877-239-5277, for assistance in applying.

**Redeterminations:**

Once determined eligible for the waiver program, an individual will remain eligible for 24 months from the date of initial eligibility, regardless of changes in income.

Every 24 months, participants will be required to re-enroll in the waiver. Prior to the enrollee's redetermination date, ACS will mail the enrollee a renewal document similar to the initial application; however, most of the enrollment data will be pre-printed on the form (e.g., name, address, date of birth, Social Security number). The instructions on the form will guide the enrollee to verify the pre-printed information, to supply any information that may have changed, to provide updated income information, and to sign and return the form within a certain timeframe. When received by ACS, the renewal form will be processed to determine eligibility for continuing benefits. If, by the due date, the form has not been returned, or has been returned incomplete, the enrollee will be notified in writing that if the necessary information is not provided within 10 days from the date of the notification, he will be disenrolled from the waiver.

**Intake, Enrollment, Disenrollment:** Applications will be available on the Internet, at local pharmacies, at Department of Social Services offices, Department of Health and Human Services office, libraries, Legislative delegation offices, and at the local offices of the South Carolina Association of the Council on Aging. Staff at the local offices for the Council on Aging will assist applicants with both hard copy and web-based applications. Individuals who apply on-line will be mailed an application and must sign and return the signature page before the application will be processed.

All applications will be forwarded to a central site and processed by ACS. No verification of age, residence, income, or other insurance is required at the time of application. Applicants will be allowed to self-declare these criteria.

ACS will verify, through an arrangement with SCDHHS, that applicants who meet waiver criteria do not receive non-demonstration Medicaid. Applicants found to be currently enrolled in non-demonstration Medicaid will be denied waiver benefits.

Applicants who apply by mail will be notified by first class mail of their eligibility or ineligibility for the waiver. Those who apply via the Internet will receive initial notification on-line. All applicants who are found eligible will be mailed identification cards and a "welcome packet" describing the waiver benefits: coverage, limitations, exclusions, co-pays, deductibles, and formulary.

Waiver eligibles will be added to the Medicaid Management Information System (MMIS). Once added to MMIS, eligibles will be subject to Third Party Liability (TPL) data matches performed for Medicaid eligibles. This process will serve as

DHHS' verification of TPL by matching SILVERxCARD enrollees against the Medicaid recipient/TPL databases. Currently, TPL data matches consist of a match with CHAMPUS. When a data match indicates third party coverage of drugs, an exception report will be generated, and ACS will follow up with the insurance company to verify that third party coverage is coverage that makes the applicant ineligible for the waiver and that it has not lapsed. If third party drug coverage does exist, the individual will be disenrolled from the waiver.

For applicants/beneficiaries failing to meet waiver criteria, a letter will explain the reason for ineligibility and will provide a reference to the policy supporting the denial or termination of benefits. Non-demonstration Medicaid policy regarding advance notice of termination will apply. The letter will advise the applicants/beneficiaries of their appeal rights and of the procedures to follow to request a fair hearing. Those found to be ineligible for the waiver but potentially eligible for non-demonstration Medicaid will be so informed and advised how they may apply.

For applicants who meet waiver criteria but cannot be approved due to the enrollment ceiling, a letter will explain the waiting list procedures, the right to appeal, procedures for requesting a fair hearing, and a reference to the policy supporting the denial of benefits.

For applicants whose eligibility cannot be determined due to an incomplete or incorrect application, a computer printed "turnaround document" indicating the nature of the problem will be mailed to the applicant, providing the opportunity to correct the problem. ACS matches returned turnaround documents to the applications pended. The new information is applied to the original application and the application is processed. If the applicant does not respond to the request for additional information, eligibility cannot be determined, and a letter of denial will be sent, including the reason for denial, a policy reference supporting the denial, information about appeal rights, and the procedures for requesting a fair hearing.

Appeals policies and procedures will be consistent with those of non-demonstration Medicaid.

**Establishment, if Applicable, of Enrollment Ceilings:** The initial group of waiver participants will consist of approximately 41,000 individuals currently enrolled in the State's pharmacy program. This number will increase as new applications are processed, and, if necessary, a waiting list will be maintained by ACS to ensure that participation is limited to 66,000 in year five.

**Determination of Scope and Existence of Existing Third Party Liability:** See Intake, Enrollment, Disenrollment section.

Coordination of Waiver with Medicaid Program Eligibility and Enrollment Processes, including Estate Recovery: **See Eligibility Determination and Intake, Enrollment, Disenrollment sections. There will be no estate claims for services provided under this waiver.**

The Process by Which Potential Waiver Enrollees Will Be Informed of the Impact of Enrollment on Current or Future Medigap Policy Purchases: **Inform enrollees that the existence of other prescription drug coverage (including Medigap policies) will prevent them from qualifying for the waiver.** An individual, who has a Medigap policy that **does not** include prescription drug coverage, is eligible to apply for the SILVERxCARD program. Additionally, subsequent enrollment in the SILVERxCARD program will not affect the individual's Medigap coverage.

In Addition to Outreach Efforts Described in h, a Description of the State Referral Systems Designed to Link Interested Individuals to the Programs for Which They Could Be Eligible: The Office of Senior and Long Term Care Services is developing information for the Department of Health and Human Services website (www.dhhs.state.sc.us) and provides counseling to assist individuals in locating programs that will provide the services they need.

## I. QUALITY

Operations and personnel will be monitored using existing managerial practices as few new personnel will be needed and existing operating systems that are marginally modified will be used. Systems management staff will use feedback from field staff and recipients to monitor issues of planning, implementation and satisfaction. Quality indicators will be developed during the pre-implementation period and will address such issues as simplification of the application system, client satisfaction with the service and overall effectiveness. The quality monitoring system is already in place and mainly consists of feedback from the public. In the evaluation plan, there are provisions for quality-monitoring surveys which will trigger action plans. The fraud and abuse provisions are already in place and incorporated into the regular Medicaid program. Physicians and pharmacies participating in the pharmacy case management service delivery will obtain medical information on a sampling of clients.

## J. GRIEVANCES AND APPEALS

The Medicaid agency maintains procedures ensuring that all providers and eligibles are granted an opportunity for a fair hearing. Procedures may be found in S. C. Regulations at Chapter 126, Article 1, Subarticle 3. An appeal hearing may be requested when payment for services is denied or when the amount of such payment is in controversy.

## K. EVALUATION DESIGN

The evaluation design is described in the original waiver application and centers around answering three questions in the areas of health, resources and health policy. Sources of data and collection methodology are also described in the application. The program will be isolated by the point of sale system from the

regular Medicaid prescription drug program. The evaluation will be contracted to a qualified consulting firm.

## L. INTERACTION WITH OTHER FEDERAL AND/OR STATE PROGRAMS

The Operational Protocol instructions ask that the state describe how pharmacy coverage under the demonstration will interact with other federal health care benefit programs/grant programs and other state health care benefit programs (e.g., Medicaid, Ryan White, and State-only funded pharmacy programs). DHHS is unaware of any state-only funded pharmacy programs with which the demonstration waiver would interact. This waiver program will be an expansion of the existing Medicaid program, granted as a Medicaid 1115 Research and Demonstration Waiver. Any interface with federal programs such as Medicare or FQHCs will duplicate the interface that the existing Medicaid program currently experiences.